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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,122	02/28/2006	Christine Power	ARS-122	7430

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
08/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,122	POWER ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-50,55 and 57-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-50,55 and 57-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 22 May 2009, have been entered in full. Claims 1-45, 51-54 and 56 are canceled. Claims 46-50, 55, 57-60 are under examination.

Claim Rejections - 35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46-50, 55, 57-60 remain rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (reference submitted by Applicant; WO 02/074961 A1). The basis for this rejection is set forth at pages 3-4 of the previous Office Action (24 February 2009).

Applicant argues that the cited prior art fails to anticipate the claim invention. Applicant cites *Net Moneyin, Inc. v. Verisign, Inc. 545 F.3d 1359, (Fed. Cir. 2008)*. Applicant states that the polypeptide corresponding to SEQ ID NO:913 is not associated with a polypeptide associated as useful for the treatment of liver or lung fibrosis and thus it cannot be said that the references teaches or suggest its use in such a treatment protocol. Applicant argues that Table 2 (from the cited reference) indicates that the

polypeptide has homology to the human SEC protein of the sec oncogene or a human hematopoietic/immune antigen. Applicant argues that polypeptide is not listed in Tables 3 or 4, thus the polypeptide was not recognized as having homology to a signature region or homology to a gene family at the time the cited reference was filed. Applicant maintains that at best, one skilled in the art, in view of the teachings of the reference, would have used the polypeptide associated with SEQ ID NO:913 in methods of detecting cancers or possibly for detecting elements of the human hematopoietic/immune systems. Applicant argues that the description of the reference would indicate that a polypeptide with similarities to an oncogene or a human hematopoietic/immune antigen would be used in assays such as those discussed on pages 47-53 and 64-66. Applicant argues that the teachings of the reference would not have indicated that the claimed polypeptide should have been used for the treatment of liver or lung fibrosis. Lastly, Applicant states that they have reviewed the database entry associated with the Q9BTA0 accession and note that the gene was isolated from melanoma. Applicant attaches a printout. Applicant contends that those skilled in the art at the time the invention was made, would not have recognized that the polypeptide of SEQ ID NO:913 should have been used for the treatment of liver or lung fibrosis.

Applicant's arguments have been fully considered but are not found persuasive. Applicant's arguments that the polypeptide has homology to the human SEC protein of the sec oncogene or a human hematopoietic/immune antigen and that at best, one skilled in the art, in view of the teachings of the reference, would have used the polypeptide associated with SEQ ID NO:913 in methods of detecting cancers or

possibly for detecting elements of the human hematopoietic/immune systems is not found persuasive because relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities. For example, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the platelet-derived growth factor (PDGF) family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity of PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). Vukicevic et al. (PNAS USA 93:9021-9026, 1996) disclose that OP-1, a member of the TGF-β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-β family members BMP-2 and TGF-β1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging columns 1-2). Even if the protein of Tang et al. has homology to a human hematopoietic/immune antigen or the human SEC protein does not mean that the protein must only be employed in methods of detecting elements of the human hematopoietic/immune system or methods of detecting cancer. Tang et al. clearly teach a 163 amino acid polypeptide that is 100% identical to instant SEQ ID NO:2, which is 163 amino acids. Tang et al. clearly teach that the composition of the present invention is useful for treatment of lung or liver fibrosis (page 55, lines 24-26).

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Art of Record

Appel et al. (European Journal of Human Genetics Vol. 10:17-25, 2002) teach keratolytic winter erythema as an autosomal dominant skin disorder characterized by erythema, hyperkeratosis and peeling of the skin. The chromosomal region has been mapped to human chromosome 8p22-p23. Appel et al. teach that one transcript shows similarity to human SEC oncogene (abstract; page 22, last paragraph-page 23). Appel et al. teach a possible correlation between human SEC protein (which has homology to the protein of Tang et al.) and keratolytic winter erythema which is a thickening of the outermost layer of the epidermis. The Appel reference is not considered art but is pertinent to Applicant's disclosure. Systemic sclerosis, which is a fibrotic disease which affects large areas of the skin (hardening, thickening) and one or more internal organs.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. M. D./
Examiner, Art Unit 1647
8/10/09

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646